

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG, ABBOTT  
BIORESEARCH CENTER, INC., ABBOTT  
BIOTECHNOLOGY, LTD.

Plaintiffs,

V.

CENTOCOR ORTHO BIOTECH, INC.,  
CENTOCOR BIOLOGICS, LLC.

Defendant.

C.A. No. 4:09-CV-11340 (FDS)

JURY TRIAL DEMANDED  
(*FILED UNDER SEAL*)

**ABBOTT'S OPPOSITION TO CENTOCOR'S *DAUBERT* MOTION TO EXCLUDE  
TESTIMONY OF ABBOTT EXPERT JOAN ELLIS**

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## **I. INTRODUCTION**

Centocor's *Daubert* motion to exclude the rebuttal testimony of Dr. Joan Ellis on priority of invention advances two speculative arguments, one based on a mischaracterization of Dr. Ellis's report and on Centocor's tenuous interpretation of the law, and the other based on a mischaracterization of Dr. Ellis's qualifications. Both arguments should be rejected.

First, Centocor's claim that Dr. Ellis's opinion is based on an erroneous legal premise is wrong both because Dr. Ellis's opinion does not turn on the issue of whether Centocor's inventors appreciated that the Stelara antibody possessed the features of the patent claims and because Dr. Ellis's understanding of the law with regard to appreciation is, indeed, correct. In addressing and rebutting the conclusion of Centocor's expert Gerald M. Murphy, Jr. on the issue of priority, Dr. Ellis personally reviewed and assessed Abbott's ample documentary evidence concerning its conception and reduction to practice and determined that Abbott had earlier reduction to practice dates on which it could rely to rebut Mr. Murphy's contentions that Centocor was the first to invent the subject matter of the asserted claims. She additionally concluded that the Centocor reduction to practice dates Mr. Murphy put forth – which follow Abbott's – were, in any case, based on insufficient evidence of priority because Mr. Murphy failed to show by clear and convincing evidence that what Centocor's inventors reduced to practice at the time possessed all the properties recited in the asserted claims and that the inventors appreciated that it contained these properties.

Centocor does not challenge Dr. Ellis's conclusion that Abbott was the first to invent the subject matter of the asserted claims as evidenced by its earlier reduction to practice dates. Instead, Centocor rehashes its summary judgment motion number 6 arguments of priority, to assert that its tenuous reading of the law on the issue of appreciation is correct, and Dr. Ellis's reading is not. Whatever constitutes the precise parameters of the "appreciation" requirement,

there is one recurring theme in the case law, to which Dr. Ellis adhered: an inventor claiming priority must have appreciated the inventive features of what he made – i.e., that he made something new – when he made it. In applying this principle, Dr. Ellis recognized that affinity, sub-unit specificity, and the requirement of an “additional agent,” as well as neutralization of IL-12, were all inventive features of the asserted patent claims that Centocor’s inventors would need to have appreciated. Therefore, Dr. Ellis’s interpretation and application of the law were correct.

Centocor’s second argument that Dr. Ellis’s testimony should be excluded because she is unqualified is also meritless. Dr. Ellis is not only a patent lawyer and former USPTO patent examiner and judge, but she is a scientist by education and training. She is educated and experienced in the relevant art and is far more qualified than Centocor’s corresponding expert, Mr. Murphy. Dr. Ellis would be helpful to the trier of fact in summarizing complex facts relating to priority of invention, without reciting the law. At a minimum, she is qualified to present a valuable overview of the file histories of the patents-in-suit and the workings of the patent and interference processes generally. In sum, Dr. Ellis’s qualifications render her testimony particularly useful, and her testimony should not be excluded.

## **II. LEGAL STANDARD**

The trial court serves a “gatekeeping” function “in regulating the admission of expert testimony” by conducting a preliminary evaluation of the reliability and relevance of the proffered expert testimony pursuant to Federal Rule of Evidence 702. *United States v. Diaz*, 300 F.3d 66, 73 (1st Cir. 2002) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589–95 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141, 147–49 (1999)).

The Rule 702 inquiry “is a flexible one, and there is no particular procedure that the trial court is required to follow . . .” *Diaz*, 300 F.3d at 74 (citation and internal quotation marks omitted). The Court enjoys “substantial discretion” in deciding whether to admit or exclude

relevant expert testimony. *Mitchell v. United States*, 141 F.3d 8, 15 (1st Cir. 1998) (citing *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997)). As this Circuit and Court have recognized, a *Daubert* motion requires the Court to carefully evaluate whether the challenge to the expert testimony goes more to the weight, rather than the admissibility of the proffered opinion. *Allen v. Martin Surfacing*, 263 F.R.D. 47, 53 (D. Mass. 2009) (Saylor, J.) (citing *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (explaining that opinion rested upon good grounds generally and should be tested by “adversarial process”); *Mitchell*, 141 F.3d at 15 (stating that expert’s lack of specialty practice in area about which he testified went to weight, not admissibility)). Indeed, challenges to the factual underpinnings of an expert’s investigation “often go to the weight of the proffered testimony, not to its admissibility.” *Crowe v. Marchand*, 506 F.3d 13, 18 (1st Cir. 2007).

Overall, the district court should consider three issues as part of this evaluation: (1) whether the proposed expert is qualified by “knowledge, skill, experience, training or education”; (2) whether the proposed subject matter of the expert opinion properly concerns “scientific, technical, or other specialized knowledge”; and (3) “whether the testimony is helpful to the trier of fact, *i.e.*, whether it rests on a reliable foundation and is relevant to the facts of the case.” *Bogosian v. Mercedes-Benz of N. Am., Inc.*, 104 F.3d 472, 476 (1st Cir. 1997).

### **III. DR. ELLIS’S OPINION ON PRIORITY SHOULD NOT BE EXCLUDED**

#### **A. Dr. Ellis’s Priority Opinion is Not Predicated on an Erroneous Legal Premise**

##### **1. Centocor Mischaracterizes Dr. Ellis’s Opinion**

Fairly summarized, Dr. Ellis’s opinion that Abbott was the first to invent the subject matter of the asserted claims as evidenced by its earlier reduction to practice dates is based on an analysis of Abbott’s documentary evidence, and not on the element of appreciation that is the

focus of Centocor's motion. Centocor's motion is premised on a distorted reading of Dr. Ellis's opinion and a key misstatement of its predicate.

Centocor incorrectly states that "[Dr.] Ellis' opinion that Centocor was not first to invent was not based on any independent analysis of the sufficiency of Abbott's evidence of invention dates" but, rather, "solely on an analysis of the sufficiency of *Centocor's* evidence . . . ."

(Centocor's Daubert Mot. to Exclude Testimony of Abbott Expert Joan Ellis and Memorandum in Support ("Centocor Mot.") at 2.) A reading of Dr. Ellis's report shows that this is plainly wrong. In composing her report, Dr. Ellis, who is a scientist and former patent examiner herself, reviewed Abbott's scientific documentation and traced Abbott's identification of some fifty antibody clones reduced to practice from 1996 to 1998. (Centocor Mot. Ex. 1, Rebuttal Expert Report of Dr. Joan Ellis, Ph.D. ("Ellis Rep.") at ¶¶ 90-91; Weiner Decl. Ex. 1, Ellis Rep. Ex. C.)

Based on this documentary evidence, Dr. Ellis [REDACTED]

[REDACTED] (Ellis Rep. at ¶¶ 91-92.) Centocor points to a deposition excerpt in which Dr. Ellis confirmed that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Centocor Mot. Ex. 2, Ellis Dep. at 144:18-145:22.) Dr. Ellis's testimony in no way diminishes the fact that Dr. Ellis assessed and relied upon Abbott's documentary evidence of earlier reduction to practice dates in forming her opinion that "Abbott was the first to invent the subject matter of the asserted claims." (Ellis Rep. at ¶ 99.) In fact, it confirms it.

Dr. Ellis additionally opined that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

*Id.* at ¶ 99.

In sum, Dr. Ellis's conclusion with respect to priority did not depend on whether Centocor's inventors appreciated the inventive properties of what they had made. Rather, it was based on the fact that Abbott's reduction to practice dates predated all the Centocor reduction to practice dates put forth in Mr. Murphy's report. Therefore, even if Dr. Ellis's report never addressed the issue of appreciation, her conclusion on priority would remain the same.

## **2. Dr. Ellis's Recitation of the Law is Correct**

In addition to mischaracterizing Dr. Ellis's report, Centocor is also incorrect in its contention that the law requires it to prove only that its inventors appreciated that they had isolated an antibody that neutralizes IL-12. The cases on this point have one recurring theme: an inventor must appreciate the inventive features of what he has made, i.e., that he made something new. Here, affinity, sub-unit specificity, and the requirement of an additional agent are key inventive features, in addition to neutralization, of the asserted claims of the patents-in-suit.

Therefore, a prior inventor would have needed to recognize these features to appreciate that he created something new.

It is telling that Centocor focused on the importance of these inventive features of the asserted claims in furtherance of its argument in opposition to Abbott's Motion for Summary Judgment No. 2 regarding collateral estoppel:



(Weiner Decl. Ex. 16, Centocor's Opp. to Pls.' Mot. for Summary Judgment No. 2 That Centocor is Collaterally Estopped From Alleging Invalidity of U.S. Patent No. 6,914,128 at 9.) Now, Centocor argues the exact opposite: that to show priority of the asserted *claims*, Centocor's inventors needed to appreciate only that they invented an antibody that met the definition of the interference *Count* – a neutralizing, human IL-12 antibody. Centocor cannot have it both ways.

The most recent Federal Circuit decision on this point, *Teva Pharmaceutical Industries Ltd. v. AstraZeneca Pharmaceuticals LP*, confirms that “[t]o establish prior invention, the party asserting it must prove that it appreciated what it had made.” 661 F.3d 1378, 1384 (Fed. Cir. 2011). *Teva* clarifies that this “appreciation” requirement does not require a prior inventor “to know everything about how or why its invention worked” or to “conceive of its invention using the same words as the patentee would later use to claim it.” *Id.* However, nothing in the *Teva* decision suggests that the limitations of the claims and their scope can be disregarded in determining whether the putative inventor “appreciated what it had made.” *Id.* Thus, while the inventors in the *Teva* case were not required to demonstrate what ingredient in their formulation

was the source of improved stability in their invented compound, they were required to demonstrate that they appreciated the fact of improved stability as required by the claims.

Analogously, as Dr. Ellis concluded, to demonstrate prior invention in the instant case, Centocor would need to show at least that it recognized that its antibody had the neutralization, affinity, and sub-unit specificity properties of the ‘128 and ‘485 patent claims, and that its pharmaceutical composition had the additional agent requirement of the ‘485 patent claims, even if Centocor would not be required to demonstrate an understanding of the characteristics of the antibody or pharmaceutical composition responsible for those properties (*e.g.*, the antibody’s epitope). (*See* Ellis Rep. at ¶ 87 (“[REDACTED]”); *id.* at ¶ 98.)

*Teva* also confirms that prior Federal Circuit cases on this point “are consistent applications of the same rule.” 661 F.3d at 1384 (discussing *Invitrogen Corp. v. Ciontech Labs. Inc.*, 429 F.3d 1052, 1065-66 (Fed. Cir. 2005) (showing of priority requires “an objective basis corroborating the inventors’ belief to show . . . that persons skilled in the art at the time of the recognition would have recognized the existence of the relevant inventive features”); *Dow Chemical Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed. Cir. 2001) (“The invention is not the language of the count but the subject matter thereby defined. [The prior inventor] must establish that he recognized and appreciated [the] new form.”) (quoting *Silvestri v. Grant*, 496 F.2d 593, 599 (C.C.P.A. 1974)); *Mycogen Plant Sci. v. Monsanto Co.*, 243 F.3d 1316, 1336-37 (Fed. Cir. 2001) (finding “sufficient evidentiary basis for a reasonable jury to find that Monsanto’s scientists appreciated the limitations of the claims of the ‘600 and ‘862 patents,” without requiring Monsanto “to have framed its prior documentation about its reduction to

practice in the exact language given in the claims.”). *See also Cooper v. Goldfarb*, 240 F.3d 1378, 1384 (Fed. Cir. 2001) (prior inventor required to show that “he knew, at the time of his alleged reduction to practice, both that the material had the properties recited in the count and that it would be useful as a graft”); *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 594-95 (Fed. Cir. 1997) (“[W]hen testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for reduction to practice to occur.”).

These cases further confirm that to appreciate what they had made, Centocor’s scientists not only needed to appreciate that they had isolated an antibody that neutralizes IL-12, but also that the antibody and subsequent pharmaceutical composition possessed the important inventive features of affinity, sub-unit specificity, and the requirement of an additional agent reflected in the asserted claims. Dr. Ellis’s report correctly reflects this understanding.

**B. Dr. Ellis’s Qualifications Render Her Testimony Helpful to the Trier of Fact**

Centocor’s assertion that Dr. Ellis’s opinion on priority should be excluded for the “additional or alternative reason” that “she has no particular qualifications or specialized knowledge that qualify her to render her opinion” should also be rejected. (Centocor Mot. at 8.) Centocor’s argument is based on the conclusory statement that Dr. Ellis’s “experience as a patent attorney does not qualify her as an expert for the purposes of rendering an opinion on the sufficiency of Centocor’s priority evidence.” (*Id.*) However, Centocor wholly ignores Dr. Ellis’s additional scientific qualifications, as well as the extent of her work as a USPTO patent examiner and judge. Not only does Centocor fail to explain why Dr. Ellis’s extensive qualifications purportedly render her unqualified, but it also disregards the potential usefulness of Dr. Ellis’s limited testimony as a summary witness.

In addition to her law degree, Dr. Ellis received a B.A. in Microbiology and a Ph.D. in Molecular Parasitology. (Ellis Rep. at ¶ 5.) She was a Damon Runyon Memorial Cancer Fund

Research Fellow for two years following her Ph.D. thesis work, and during her six years as a graduate student and post-graduate fellow, Dr. Ellis’s “research focused on the cloning and characterization of malarial antigens.” (*Id.* at ¶ 6 and attached Ellis curriculum vitae.) In fact, she “was the first to clone a malaria antigen” and is the inventor on at least one patent relating to such work. (*Id.*)

In 1987, Dr. Ellis began her work in the USPTO as a patent examiner, specializing in biotechnology. (*Id.* at ¶ 7.) She “examined hundreds of patent applications in the pharmaceutical and biotechnology art and determined their patentability.” (*Id.* at ¶ 8.) In 1993, she received an Examiner Ph.D. Level Classification. (*Id.* at ¶ 10.) “This is the highest classification rating a patent examiner can achieve,” recognizing “that the examiner is an authority in his or her technology and that the patent applications he or she examines embrace technical concepts that cannot be acquired in a bachelors/masters curriculum.” (*Id.*) Dr. Ellis was also awarded the American Intellectual Property Owner’s Outstanding Examiner of the Year Award “in recognition of the quality and complexity” of her work in 1994. (*Id.* at ¶ 11.) The following year, she was promoted to the USPTO Board of Appeals and Interferences, where she worked as an Administrative Patent Judge for eleven years, rendering final agency decisions on patentability in both *ex parte* and interference proceedings. (*Id.* at ¶ 12.) After nearly twenty years, Dr. Ellis retired from the USPTO in 2006 and went into private practice, where she has continued her work as a patent lawyer. (*Id.* at ¶ 14.)

Centocor itself cites case law confirming that Dr. Ellis is qualified not only “to speak to matters bearing upon the patenting process, the workings of the U.S. Patent and Trademark Office, and the duties of a patent attorney,” but also to “offer more expansive testimony” based on her “education, experience, and training . . . in the particular field at issue.” *Hem, Inc. v.*

*Behringer Saws, Inc.*, No. 00-CV-0331-EA(J), 2002 WL 34698060, at \*2 (N.D. Okla. Oct. 18, 2002). Unlike the patent attorney in *Hem*, who did not have “any significant experience or education in the relevant art,” *id.*, Dr. Ellis does have significant experience and education in the relevant art. Indeed, Dr. Ellis is more qualified than Centocor’s expert, Mr. Murphy, whom Centocor has informed Abbott it intends to call at trial. (Weiner Decl. Ex. 2, Verrecchio letter to Weiner, dated July 2, 2012.) Mr. Murphy’s primary experience is as a patent attorney in private practice and his only arguable connection to the relevant art is a B.S. in microbiology, an M.D., and one year of work as a lab technician. (Weiner Decl. Ex. 3, Murphy Rep. at ¶¶ 5-7 and attached Murphy curriculum vitae.) Unlike Dr. Ellis, Mr. Murphy has no significant experience or graduate training in the relevant art, and he has never worked for the USPTO.

Dr. Ellis’s education and experience make her more than qualified to review and assess the scientific evidence in this case, and to provide her opinion regarding the facts relating priority, without testifying as to matters of law. *See also Fiataruolo v. U.S.*, 8 F.3d 930, 941 (2d Cir. 1993) (accountant allowed to testify that based on evidence he reviewed and work he did, he concluded that one of plaintiffs was not responsible for payment of taxes); *Bone Care Int’l. LLC v. Pentech Pharms., Inc.*, No. 08-CV-1083, 2010 WL 3928598, at \*15 (N.D.Ill. Oct. 1, 2010) (“[Expert] may provide factual context that goes to the underlying contentions of inequitable conduct, obviousness, priority, and other key legal issues, but he may not speculate or offer his subjective conclusions on those contentions.”); *Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F. Supp. 2d 252, 257 (W.D.N.Y. 2000) (patent law expert allowed to testify regarding effective filing date of patent, provided testimony also includes factual basis). Indeed, Dr. Ellis is qualified to provide the trier of fact – here, the jury in the infringement action and the Court in the section 146 action – with a helpful explanation and summary of the relevant facts in

evidence. *See U.S. v. McElroy*, 587 F.3d 73, 82 (1st Cir. 2009) (approving use of IRS agent and insurance fraud investigator as summary witnesses under Federal Rules of Evidence 1006 and 611(a) because “testimony did no more than analyze facts already introduced into evidence and spell out the tax consequences that necessarily flow from those facts.” ) (internal quotation marks omitted). Such a summary would certainly assist the jury’s and the Court’s understanding of the complex, technical facts relating to priority of invention. *See Cipollone v. Yale Indus. Prods., Inc.*, 202 F.3d 376, 380 (1st Cir. 2000) (describing the “ultimate purpose of the *Daubert* inquiry” as determining the testimony’s helpfulness to the jury).

At a minimum, Abbott would offer Dr. Ellis to present the trier of fact with an overview of the asserted patents’ file histories and the patenting and interference processes generally. *See Bausch & Lomb*, 79 F. Supp. 2d at 256 (permitting patent law expert “to testify about the ‘nature and purpose’ of both interference and reexamination practice and procedure, including the terminology commonly used in those procedures”). Such technical concepts are beyond a layperson’s knowledge and properly explained by an expert. *See Levin v. Dalva Bros.*, 459 F.3d 68, 79 (1st Cir. 2006) (“Expert testimony on industry standards is common fare in civil litigation.”). Indeed, Centocor itself concedes that Dr. Ellis’s experience as a patent attorney makes her qualified to, at least, provide testimony about “the patenting process [and] the workings of the U.S. Patent and Trademark Office.” (Centocor Mot. at 8 (quoting *Hem*, 2002 WL 34698060, at \*2).)

Therefore, Dr. Ellis’s testimony – summarizing the facts relating to priority, and, at a minimum, explaining the patenting and interference processes – would be especially helpful to the jury and to the Court, and it should not be excluded.

#### IV. CONCLUSION

For all of the reasons set forth above, Abbott respectfully requests that the Court deny Centocor's *Daubert* Motion to Exclude the Testimony of Abbott Expert Joan Ellis.

Dated: July 13, 2012

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I certify that, on July 13, 2012, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Robert J. Gunther, Jr.

Robert J. Gunther, Jr.